

REMARKS

In the present Office Action, Examiner Ramana maintained a rejection over the Sertich reference, and suggested an amendment regarding that reference. She also relied on previously uncited disclosure from the Beyar reference in a rejection. As noted below, her suggestion is being accepted, and she is respectfully requested to reconsider and withdraw her rejections.

Examiner's Suggestion Regarding Sertich Reference

The present Office Action includes a rejection of claims 37, 42-47, 49, 51-52 and 55-62 over U.S. Patent No. 5,800,500 to Sertich. The remarks concerning Sertich made in the previous response are believed apt, and for the sake of space are not repeated but are incorporated herein by reference. Additionally, the rejection does not provide a sufficient explanation of where each feature of the independent claims are found, and has no particular discussion at all of any features of the dependent claims. On that basis, it is respectfully noted that a *prima facie* case of anticipation over Sertich has not been made, and so the rejection should be withdrawn.

Applicant thanks Examiner Ramana for her suggestion of an amendment that would, in her view, overcome the Sertich reference. As noted above, it is not believed that unpatentability of these claims over Sertich has been shown, and therefore no amendments are necessary. However, to move this case more quickly toward allowance, the Examiner's suggested amendment is being made. Withdrawal of the rejections over Sertich is respectfully requested.

Finality Should Be Withdrawn

The Examiner is requested to withdraw the finality of this rejection. The previous Office Action relied on Figures 28-31 and columns 14-16, half each of columns 27 and 28, and columns

31-37. The current Office Action, on the other hand, relies on Figures 12-13C, the last half of column 29, column 30 and the first four lines of column 31. The prior Office Action alleged anticipation by disclosure different from that relied on in the current Office Action.

This is a new ground of rejection not necessitated by an amendment. MPEP 1207.03 (referenced by MPEP 706.07(e)) speaks briefly to new grounds of rejection: "Where the statutory basis for the rejection remains the same, and the evidence relied upon in support of the rejection remains the same, a change in the discussion of, or rationale in support of, the rejection does not necessarily constitute a new ground of rejection" (citing *In re Kronig*, 539 F.2d 1300, 1303, 190 USPQ 427 (CCPA 1976)). Here, while the statutory basis is the same, the evidence used to support the rejection is different. This is not a case in which the Examiner changed a rationale or discussion of given structure, ostensibly through the eyes of one of skill in the art. Rather, even though from the same reference, new material is relied on. For example, the prior Office Action called "rods" on a balloon the first and second portions recited in claim 37, but the current Office Action asserted that top and bottom portion of items 125 or 130 were those portions. The new rejection is not merely a change in reasoning concerning the same disclosure, but requires new and different disclosure. Applicant has not had an opportunity to react to this ground of rejection.

The Beyar Reference Does Not Show All Elements of Any Claim

Moreover, Beyar's Figures 12-13C and its text in columns 29-30 and into column 31 do not show all features of any of the claims. Claim 37 recites a delivery instrument including an expandable element along a distal portion thereof. The Office Action characterizes the disclosed syringe as a "delivery instrument" and argues that a balloon (col. 30, ll. 28-32) is the recited expandable element. Claim 37 further states that the recited expandable device is removably

mountable to the expandable element with each in an unexpanded condition. Beyar's items 125 and 130 automatically expand when expelled from the syringe, and before any insertion of a balloon within them. Neither of them are mounted on a balloon in an unexpanded condition. Further, forcing an unexpanded balloon inside an unexpanded item 125 or 130 so that the item is mounted on the balloon is at least partially inoperable because of the likelihood of damage to the balloon as it scrapes across the interior length of the item 125 or 130, which includes the edges of the openings 120 and/or the teeth 119. A mounting of an expandable device on an expandable element with both unexpanded is not shown or suggested in the Beyar reference.

The Beyar disclosure in columns 29-30 also does not show a delivery instrument including an expandable element along a distal portion of the delivery instrument. The Office Action alleged that Beyar's syringe is a "delivery instrument," and Beyar discloses a "balloon inserted through the syringe" (col. 30, l. 31). The balloon is not stated as being included as a part of the syringe, and it cannot be since the syringe must be unblocked in order to allow an item 125 or 130 to pass through. If the syringe included a balloon on the inside, then item 125 or 130 would have to somehow pass through the balloon. If the syringe included a balloon on the outside, the balloon (and the syringe exterior) is larger than the inside of item 125 or 130, and cannot be used to expand the item. Moreover, the balloon disclosed in Beyar must extend from the end of the syringe, rather than along the distal part of it. The balloon cannot expand the item 125 or 130 if it is along the inside of the syringe.

Claims 38-40, 42-49 and 51-52 are dependent from claim 37, and are allowable on at least that basis. It is noted that the Office Action did not discuss all of these dependent claims or present a *prima facie* case of anticipation of them over the Beyar reference. Accordingly, these claims should be allowed as well.

As one example, the Office Action did not address claim 40, which recites that the delivery instrument includes a shaft defining a lumen in fluid communication with the interior of the expandable element. Nothing in Beyar discloses or suggests the inside of a syringe being in fluid communication with a balloon that is inserted through it. If the inside of the balloon is in fluid communication with the inside of the syringe, then the balloon must block the end of the syringe. If it does not block the syringe, then pressure intended to inflate the balloon will escape through the end of the syringe. If it does block the syringe, then the item 125 or 130 cannot pass through the syringe.

Claim 43 recites that the first and second portions of the expandable device are unidirectionally movable away from each other on expansion of the expandable element. This feature is also not discussed in the Office Action. Diametrically-opposed parts of items 125 and 130 move not only away from each other, but along an arcuate or pivoting path as well, as the overlap in the item lessens during expansion.

Claim 44 recites that expandable device in an expanded configuration has a height between distal ends of the first and second portions that is different from a height between proximal ends of the portions. This feature is not discussed in the Office Action, and there is no disclosure in Beyar of differing heights at opposite ends. The overlapping configuration of items 125 and 130 make clear that uniform expansion will result, and the teeth 119 in item 130 will not operate as intended if there is non-uniform expansion.

Claims 45 and 46 are dependent from claim 44. They further recite particular differing-height configurations that were not discussed in the Office Action, and are not shown or suggested in the Beyar reference.

Independent claim 55, similar to claim 37, recites a delivery instrument including a non-rigid expandable element along a distal portion of the delivery instrument. As discussed above, Beyar's balloon is not included in its syringe, and the balloon extends beyond the syringe, not along a distal portion of it.

Claims 56-62 and 64-65 depend from claim 55, and are allowable on that basis and/or on their own merit. In particular, claims 58-60 recite language similar to that in claims 44-46, discussed above.

Entry and Consideration of an Amendment to Claims 37 and 55 is Respectfully Requested

For at least the above reasons, claims 37 and 55 are allowable over Beyar. However, in the interest of moving this application forward more quickly, an additional amendment is being made to place the expandable element along the exterior of the distal portion. Beyar specifically discloses inserting its balloon through its syringe for expansion beyond the syringe. The syringe is used to hold open a damaged disc area, or to remain outside of it while operations are performed. The structures cannot be modified to include a balloon placed on the outside of the syringe consistent with Beyar's other descriptions of the use of the balloon and syringe.

Support for the amendment is found at least in Figures 1-6 and 9-12 and associated text. No new matter has been added.

This amendment should be entered at least because the finality of this action should be withdrawn, as discussed previously. Further, it will remove an issue from this case, and the claim is already being amended pursuant to the Examiner's suggestion. Entry and consideration of this amendment is respectfully requested.

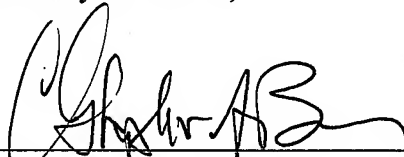
Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion.

Applicant reserves the right to later contest positions taken by the examiner that are not specifically addressed herein. No narrowing amendments have been made, and no narrowing of the scope of the claims via the remarks above is intended or should be inferred.

Reconsideration and passage to allowance in view of the above remarks is respectfully requested. Should it be determined that any further issues are outstanding, Examiner Ramana is encouraged to telephone the undersigned.

Respectfully submitted,



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